Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
Sent: 9/22/2017 10:58:04 AM
To: Thayer, Kris [thayer.kris@epa.gov]
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Here is my thought:

- **Ex. 5 - Deliberative Process**

T.

From: Thayer, Kris
Sent: Friday, September 22, 2017 6:42 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Thanks for the background and ugh on timeline.

Ex. 5 - Deliberative Process

I'm thinking we need to have the Monday briefing before we can respond to RIVM?

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: *"It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."*

From: Bahadori, Tina
Sent: Friday, September 22, 2017 6:36 AM
To: Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

How likely? I am going to go for it in full tiger mama form, but I don't know if it will be possible. Lou will likely say not.

I have mentioned to Barbara and Andrew at different times, but I don't know if they necessarily thought this would even be possible. I have also talked to Andrew about the possibility of sharing the overview document with RIVM. But I have not mentioned to David. We will assess all of this after Monday's briefing.

Ex. 5 - Deliberative Process

This request from RIVM, I think we can respond to it and somehow accommodate it, no?? Is there resistance??

T.

From: Thayer, Kris
Sent: Friday, September 22, 2017 5:00 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: FW: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

How likely do you think it is that we will be able to share the FA overview document as part of NAS review?

Do David, Andrew, Barbara and others know that is something that is being explored?

From: Lidka Maslankiewicz [mailto:lidka.maslankiewicz@rivm.nl]
Sent: Friday, September 22, 2017 4:54 AM
To: Kraft, Andrew <Kraft.Andrew@epa.gov>
Cc: Bussard, David <Bussard.David@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Els Smit <els.smit@rivm.nl>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Joke Herremans <joke.herremans@rivm.nl>; Paul Janssen <paul.janssen@rivm.nl>; Thayer, Kris <thayer.kris@epa.gov>; Theo Vermeire <theo.vermeire@rivm.nl>
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Andrew and Barbara

Thank you for your reply, apologies for not answering sooner.

The issue is that we would like to use the data as presented in the 2010 Draft, more specifically the quantification of cancer risks for NPC (Nasopharyngeal Cancer), based either on human data and on animal data.

From your mail, we understand that the information is not to be cited as the EPA position. That was not our intention, but rather we want to include the unit risks as a scientific approach that has been developed and that we need to take on board.

Could it be possible to use the information, if we explicitly include a disclaimer? Something in line with: *"It should be noted that the methodology used for the quantification of cancer risk for NPC (Nasopharyngeal Cancer), has not been formalised and should not be seen as the official position of the EPA. From a scientific viewpoint, however, we consider this approach as valid and use unit risk to derive the Maximum Permissible Risk (MPR)."*

We also noted that in 2014 US-EPA convened a workshop (https://www.epa.gov/sites/production/files/2014-12/documents/formaldehyde_workshop_agenda_final.pdf), the topics of which were the endogenous formation of formaldehyde and its relation to formaldehyde toxicity and the mechanistic evidence for lymphohematopoietic cancer induction by formaldehyde. Any further information on these topics and on the envisaged timeline for finalization of the US-EPA IRIS evaluation would be very welcome.

Maybe we can first do the exchange via mail and decide later on if a telephone conference is useful.

Kind regards

Lidka

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Centre for Safety of Substances and Products
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From: "Kraft, Andrew" <Kraft.Andrew@epa.gov>
To: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>,
Cc: Els Smit <els.smit@rivm.nl>, Paul Janssen <paul.janssen@rivm.nl>, "Joke Herremans" <joke.herremans@rivm.nl>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Bussard, David" <Bussard.David@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>
Date: 09/08/2017 05:21 PM
Subject: Re: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Hi Lidka,

Barbara (Glenn) and I are the current chemical managers of the formaldehyde assessment . We were hoping we might be able to set up a phone conversation to talk through the current status of the assessment and your questions below? If so, I can send out some type of Google poll or similar to find a time that works for everyone who might want to participate?

I would emphasize to you that the draft you mention was never finalized after it was released for the purposes of peer consultation and review. Thus, it should not be cited as an EPA position. We can explain this in greater detail when we talk.

We look forward to future conversations,
Andrew and Barbara

From: Lidka Maslankiewicz <lidka.maslankiewicz@rivm.nl>
Sent: Tuesday, August 29, 2017 7:59 AM
To: Kraft, Andrew
Cc: Els Smit; Paul Janssen; Joke Herremans
Subject: Request for permission to use data from IRIS Toxicological Review of Formaldehyde (Inhalation)

Dear Dr Kraft,
My name is Lidka Maslankiewicz and I work at the Dutch National Institute for Public Health and the Environment (RIVM). We are currently busy with the update of the Maximum Permissible Risk (MPR) for formaldehyde.
We would like to use the approach and values described in IRIS Toxicological Review of Formaldehyde (Inhalation) (External Review Draft 2010), in particular Volume 3: "Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response"

(https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614), to derive MPR value for the Netherlands. Could you, please, inform me, if this could be permitted? Are there more recent versions of this document? If we would be allowed to use your data, how we could refer to the source?

IRIS Toxicological Review of Formaldehyde (Inhalation ...
cfpub.epa.gov
EPA announces the release of the Toxicological Review of Formaldehyde-Inhalation Assessment in the June 2, 2010 Federal Register Notice. This draft assessment is ...

Kind regards
Lidka

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